



FOR IMMEDIATE RELEASE

InfraRedX Initiates a Randomized Clinical Trial of LipiScan IVUS™ Coronary Imaging Guidance to Prevent Heart Attacks During Stenting

CANARY to Assess if LipiScan IVUS™-Guided use of an Embolic Protection Filter Reduces the Rate of Heart Attacks

BURLINGTON, Mass. – July 13, 2011 – [InfraRedX, Inc.](#), a medical device company providing intelligent cardiovascular diagnostic imaging technologies, today announced enrollment of the first patient in its Phase 2 clinical trial, CANARY (Coronary Assessment by Near-infrared (NIR) of Atherosclerotic Rupture-prone Yellow). CANARY is designed to test the hypothesis that NIR-guided use of an embolic protection device (EPD), or filter, during percutaneous coronary intervention (PCI) can reduce the rate of peri-procedural heart attacks in patients identified as having high-risk lipid core plaques (HR-LCPs). InfraRedX's LipiScan™ IVUS System is the only multimodality coronary imaging device approved in both the U.S. and Europe. It is in routine clinical use to detect the LCPs known to complicate stenting and suspected to cause most heart attacks.

"We are pleased to initiate this important randomized trial testing the unique diagnostic capabilities of LipiScan IVUS to guide use of a treatment capable of preventing embolic infarction," said James E. Muller, M.D., chairman, founder and chief medical officer of InfraRedX.

Multiple studies indicate that approximately 10 percent of patients undergoing PCI experience a heart attack during the stenting procedure. There is considerable clinical evidence indicating that such heart attacks are caused by disruption by balloon dilation of large LCPs. The contents of these plaques are then carried downstream and occlude the small coronary arteries. LipiScan IVUS can detect the large LCPs most likely to cause this problem, and thereby identify cases in which a distal protection filter might be most effective.

"We will test the hypothesis that LipiScan IVUS, by detecting large lipid core plaques that are prone to embolization when dilated, can identify the subset of coronary patients in which a device designed to prevent distal embolization will be effective," said Gregg W. Stone, M.D., professor of medicine, director of cardiovascular research and education, Center for Interventional Vascular Therapy, Columbia University Medical Center, and principal investigator of CANARY. "A positive result of CANARY will be a step forward in efforts to enhance the safety of coronary stenting."

CANARY is a prospective, multicenter, randomized, open-label Phase 2 trial expected to enroll 108 patients at 10 clinical sites in the U.S. Patients identified as having a HR-LCP are randomized 1:1 to standard treatment (angioplasty and stent implantation) or standard treatment plus the use of a filter designed to prevent embolization. Subjects whose target lesion does not contain HR-LCP are assigned to standard therapy; these subjects are not randomized.



The primary efficacy endpoint in the study is reduction in peri-procedural MI, which is defined as an elevation of cardiac biomarkers. The primary safety endpoint is the occurrence of adverse events collected between discharge and one year post-procedure.

Boston Scientific is providing the FilterWire EZ™ Embolic Protection System for the study.

About the LipiScan IVUS™ Coronary Imaging System

The LipiScan™ IVUS Coronary Imaging system received U.S. Food and Drug Administration approval in June 2010 and CE Mark approval for marketing in Europe in April 2011. The system includes the world's first and only cardiac catheter to combine intravascular ultrasound (IVUS) and near-infrared (NIR) spectroscopy to help cardiologists identify and characterize lipid core coronary plaques. In a single catheter pullback, the LipiScan™ IVUS provides physicians with a traditional IVUS image that clearly displays key structural parameters of the lesion, including its location, length, degree of stenosis, and plaque burden in addition to confirming proper stent placement. At the same time, the system performs spectroscopic analysis of optical data to produce a Chemogram™ map that indicates the location of lipid core plaques and quantifies their lipid core burden. Integrating and co-registering the Chemogram with IVUS provides immediate and valuable information to interventional cardiologists during the cardiac catheterization procedure.

About InfraReDx, Inc.

InfraReDx, Inc. is a privately funded medical device company improving patient care through the development and commercialization of intelligent imaging technologies to improve the diagnosis and treatment of coronary artery disease. InfraReDx's LipiScan™ IVUS Coronary Imaging System includes the first and only available catheter to combine both near-infrared spectroscopy (NIR) and intravascular ultrasound (IVUS) technologies to characterize both the structure and composition of intracoronary plaques and identify lipid core plaques demonstrated to complicate stenting and suspected of causing the majority of heart attacks. Founded in 1998, InfraReDx is headquartered in Burlington, Massachusetts. For more information, visit www.infraredx.com.

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